

**K892118 NON-STERILE MASKS AND CAPS**Apr 20, 1989  
21 days to decisionK892118 · Product code: **FYA** · General HospitalSource: <https://www.510kdatabase.net/k892118/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Mar 30, 1989
Decision date	Apr 20, 1989
Days to decision	21 days
Third-party review	No

**APPLICANT**

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Company	<b>Paramount Products, Inc.</b>
Location	Miami, FL, US
Contact	ROBERT SIDNEY
510(k) history	2 submissions · 2 cleared · 1989-1989

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k892118/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated July 8, 2026